

## Additional Methodology Issues—Phase I—Butte Health Study

Submitted by:

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Please consider the following as additional public input regarding Phase 1 of the Butte Health Study. In this paper I have compared the methodology used for Phase 1 of the Butte Health Study to standards expressed in several articles by leaders in the field of environmental epidemiology and toxicology. My conclusion is that the methodology used in Phase 1 of the Butte Health Study has serious problems and should be redone.

### **Please consider the following:**

*Hal Morgenstern and Duncan Thomas, "Principles of Study Design in Environmental Epidemiology," Environmental Health Perspectives Supplements, vol. 101, supplement 4, December 1993, pp. 23-38. "The purpose of this article is to discuss the principles of study design and related methodological issues in environmental epidemiology. The focus is on studies aimed at evaluating causal hypotheses regarding exposures to suspected health hazards."*

This article is certainly germane to the methodology of Phase 1 of the Butte Health Study. If the causality arguments in Phase I are weak, as I believe they are, the whole Phase 1 should be redone. The article raises the following issues that have not been correctly or adequately addressed in Phase I of the Butte Study.

1. Failure to properly specify population parameters.
2. Failure to deal with the problem of long latent periods.

3. Failure to consider errors of exposure measurement and exposure misclassification bias
4. Selection Bias
5. Information Bias
6. Confounding including confounder misclassification.
7. Lack of covariate data
8. Methodology not suited to rare outcome events in non-clinical populations
9. Treating exposure as a fixed variable
10. Failure to do any cross-sectional studies. By not doing any cross sectional studies the Health Study inadequately characterizes the population of concern.
11. Failure to do any case-control studies
12. Failure to do any genetic studies
13. Failure to do any space-time cluster studies
14. Failure to do any time trend studies
15. Failure to deal with ecological biases such as within-group confounding, confounding by the group and effect modification by the group
16. Failure to do any multiple-group studies
17. Collinearity
18. Temporal ambiguity of cause and effect
19. Migration
20. Poor ecologic inference making
21. Poor quality measurements
22. Poor consideration of gene-environment interaction

***Lesley Rushton and Paul Elliott, "Evaluating evidence on environmental health risks," British Medical Bulletin, Vol. 68, Issue 1, pp. 113-128.***

This article has much to say of relevance to the issue that Phase 1 of the Health Study fails to consider environmental justice issues. "Assessment of the impact of a potential adverse health effect from an environmental pollutant is dependent on an understanding of several important issues, including: 1. The hypothesized health outcome or toxics effect, 2. The nature of the exposure, 3. The relationship between dose and response and 4. The variability and susceptibility of the

potentially exposed population, for example regarding sub-groups of the population that might be at especial risk due either to the pattern and distribution of exposures in the population, or to non-environmental factors that might influence the risk of disease.”

The Butte Health Study ignores the above issues that should have been considered in Phase I of the study.

“In environmental epidemiology, concern usually centres on chronic effect from low-level exposures.” Yet the study only looks at acute effects.

Phase I fails to consider SES of the target population as a confounding factor.

Phase I fails to consider “whether the effect on disease outcomes of one factor is modified by levels of another factor, so-called *effect modification or interaction*. “

Phase I suffers from mischaracterization due to an imperfect appreciation of the mechanisms by means of which lead exposure influences the effect of lead exposure. No individual variation is considered in Phase I.

Phase I suffers from the failure to do Bayesian modeling.

No attempt is made in Phase I of the Health Study to assess the risks to low-income citizens posed by lead exposure.

Phase I also suffers a major problem in that there is no statistical or other evidentiary support given for assuming that the population studied is representative of the low-income population in Butte. It is just assumed that because many WIC program participants were tested and WIC is a low-income program that we have an adequate sample of low income citizens in Butte.

***G.M. Paddle and J. M. Harrington, “Environmental epidemiology—strengths and weaknesses,” In. Arch Occup Environ Health (2000) 73: pp. 7-14***

According to the authors a sound study should:

1. “Communicate, express concern and indicate that the report will be systematically investigated.”

2. Give some description of the track record of exposure, particularly exposure clusters
3. Precisely define exposure and health effects and use appropriate data. (The Health Study just assumes the data is appropriate. It is interesting that only the people conducting the study can look at the raw data.)
4. "Investigate the claim of causality using Bradford Hill's criteria."
5. Set up an independent hypothesis testing study.
6. Document all steps of the process clearly.

The Health Study so far has failed to do steps 1-6.

As far as data collection is concerned, the Health Study has failed to:

- A. Specify whether or not a particular piece of data or set of data is necessary for the Study.
- B. Specify how it has accurately been collected.

Although "Social deprivation has to be recognized as a powerful confounder" the Health fails to look at social deprivation in the Health Study as a confounding factor.

Given that there is no randomization in the populations studied imbalances in the characteristics of those exposed can occur.

Selection bias can occur. (*Grimes and Schulz, "Cohort studies: marching toward outcomes," The Lancet, Vol. 359, January 26, 2002.*) I cannot find how the current Health Study avoids selection bias. It seems to be rampant throughout the study.

The above article lists the following as steps/questions to take to avoid selection bias. These steps were not taken in the Health Study nor were these questions asked.

- a. Were only people at risk of the outcome included? No, the Health Study has not,
- b. Was the exposure clear, specific, and measurable? No, the Health Study has not,

- c.
- d. Were the exposed and unexposed groups similar in all important respects except for the exposure? No, the Health Study has not,

The above article also lists the following steps/questions to minimize information bias. These steps were not taken in the Health Study nor were these questions asked.

- a. Was the outcome clear, specific and measurable? No
- b. Was the outcome identified on the same way for both groups? No
- c. Was the determination of outcome made by an observer blinded as to treatment? Definitely not.

The above article also lists the following steps/questions to minimize confounding factors and to control for confounding factors in the analysis. These steps were not taken and these questions were not asked in the Health Study.

- a. Did the investigators anticipate and gather information on potential confounding factors? No
- b. What method(s) were used to assess and control for confounding? This was a significant failure in the Health Study. Confounding factors were ignored.

The Health Study was marked by control failures as well as failure to assess outcomes equally

In dealing with causality, I am once again struck for the Health Study's failure to abide by Hill's Criteria for Causality:

- A. Strength
- B. Consistency
- C. Specificity
- D. Temporality
- E. Biological gradient
- F. Plausibility
- G. Coherence

The Health Study makes numerous causal arguments which violate Hill's criteria. The whole Health Study is in essence a study of causality. If the methodology used to establish whether or not causal links were present is unacceptable, the conclusions of the Health Study become very problematic.

I hope that these comments will be taken seriously. In the past few responsiveness summaries, the EPA has responded in a cursory and dismissive fashion.

Responsiveness summaries are one means by which the agency can show that public input really has an impact on Superfund activities. If this responsiveness summary becomes another example of a perfunctory response by EPA to public comment the EPA is not meeting its community involvement mandate.

Please consider the following as it applies to the role of community involvement in the development of Phase I of the Butte Health Study:

If men were angels, no government would be necessary. If angels were to govern men, neither external nor internal controls on government would be necessary. In framing a government which is to be administered by men over men, the great difficulty lies in this: you must first enable the government to control the governed; and in the next place oblige it to control itself. A dependence on the people is, no doubt, the primary control on the government; but experience has taught mankind the necessity of auxiliary precautions. (James Madison, *Federalist 51*)

Who will guard us from the guardians? (Juvenal)

The Superfund decision-making process mandates public involvement and numerous institutional mechanisms are provided for public comment. The EPA has a policy mandate that holds that it is: "imperative that EPA pay close attention" to citizen input and that citizens need to be "involved in the decision-making process." (OSWER 9230.0-18-"Incorporating Citizen Concerns into Superfund Decision-making.") The Introduction of the EPA's *Superfund Community Involvement Handbook* (April 2002) notes that the EPA is committed to "early and meaningful community participation during Superfund cleanup." The agency goes on to say that community involvement and participation in decision-making is a

“foundation” of the Superfund program. The *Handbook* talks about citizens “shaping” Superfund decisions. The *Handbook* further notes: “Superfund community involvement is not a public relations effort to sell the Agency or its plans to the community, nor is it just the communication of information. Community involvement is the vehicle EPA uses to get community concerns and interests to the decision-making table.” EPA endorses the core values of the International Association for Public Participation that in part include “the promise that the public’s contribution will influence the decision.” Community concerns should be reflected in agency decisions. (OSWER 9230.0-99, “Early and Meaningful Community Involvement”) In its description of the Superfund process in the January 2000 booklet *This is Superfund*, the statement is made that there is community involvement throughout the Superfund process. (p. 8) The above comments present a rather strong commitment on EPA’s part to the efficacy of public participation.

Certainly, the EPA provides numerous institutionalized vehicles of public participation—public meetings, public hearings, comment periods, etc. But the question is whether or not public participation is efficacious or do these venues of participation simply provide environmental theatre and stylized ritual. Does public comment matter? Are the forms of participation at best giving citizens the feeling that they participate in decision making without giving citizens the power to influence decisions? Is there participatory form without substance? Should citizens bother to participate in the process? This issue came to the fore recently with regards to the BSB Health Study mandated by an EPA unilateral order, the Five-Year Review of Butte Superfund sites and the ongoing discussion surrounding the Butte Priority Soils Operable Unit. People raise the legitimate question whether or not they are wasting their time in commenting when their comments seem to have no effect.

Although the EPA has a strong mandate to involve that public regarding the development and implementation of environmental rules and regulations, this mandate does not guarantee the efficacy of public participation in Superfund decision making in Butte. Often agency personnel express exasperation at low levels of public participation in agency functions. The question often gets asked: How can we increase public participation and get more citizens involved?

My answer is that citizens will be involved if three conditions are met:

1. Citizens must know the issue, i.e. are aware of the issue.
2. Citizens must see why the issue is important to them
3. Citizens must feel that their participation will have some efficacy.

If citizens don't participate, at least one of the above conditions are missing. If citizens are not participating, the EPA should not blame citizens but should evaluate the effectiveness of the agency's public involvement activities.

This discussion will examine three issues: (1) What **should be** the role of public participation in Superfund decision making, (2) What **is** the role of public participation in Superfund decision making, and (3) **How can** public participation in Superfund decision making **be enhanced**. *The focus of this discussion will be the Superfund process in Butte.*

### ***What should be the Role of Public Participation in Superfund Decision Making***

While it is indisputably the case that the EPA and MDEQ are necessary for the administration of environmental policy and the implementation of environmental programs, it is also the case that the authority of these agencies springs from the governed. The bureaucracy exists to provide services to the public and to promote the general welfare. Authority is transferred to the bureaucracy in order to achieve some public purpose and accrue some public benefit. Any exercise of bureaucratic power necessarily diminishes individual liberty. Any rule or regulation necessarily prescribes or proscribes or prohibits certain individual action. Under what conditions is this justifiable?

Justification can only come if the public impacts agency decisions and forms agency decisions.

It is a basic tenet of democratic decision making that: "on all matters where social action is substituted for individual action, liberty exists only through participation either in decision making or in control of leaders who make the decisions."

(Emmette Redford-*Democracy in the Administrative State*.) It is not just the ethics of democracy that mandates citizen participation, but the quality of public decisions is enhanced by public participation. The more people who are substantively involved in making a decision, the more information and the more perspectives that are brought to that decision. Public participation means that more alternative solutions are considered and the resulting decision will have greater credibility and legitimacy. Meaningful public participation promotes public civic education and increases trust in government institutions. Efficiency is also enhanced by public participation in that public acceptance of an agency decision decreases the likelihood of prolonged challenges to that decision. The law also mandates that most public agencies take into account public comments in rendering their decisions.



Yet, research has indicated that only about one-third of public comments are accepted by decision-making agencies. There are a number of reasons, whether valid or not, for this limited public role: (1) The public does not speak with one voice-segments of the public support a decision, segments oppose it. (2) Not all public comment is of equal discernment and environmental decision-making is not a popularity contest. (3) Agencies have invested their prestige in preferred decisions. (4) There is a view that it is government that is supposed to aggregate all of the articulated interests into sound public policy. (5) Government decision-makers are influenced by their own interests, values and perceptions. (6) Agency personnel see themselves as professional scientists and/or engineers who possess the technical expertise to make the right environmental decisions. Their view is that the ordinary public does not possess this technical discernment. (7) There is a distrust of the public and a view that public participation is often too time consuming, wastes money, and allows for too much obstructionism. There are government officials who would prefer to leave the decisions to the government experts and not needlessly complicate matters by involving the public. I recall the comment of one EPA official, I believe in Ohio, who remarked that they had a pretty good decision until the public got involved and messed it up.

There are also structural limits to the extent of public participation.

1. It is a basic principle of government, particularly democratic government, that government agencies, such as EPA, have to aggregate all of the articulated public interests into some decision. Governing means to choose and deciding means choosing between alternatives and those whose alternatives are not selected will be disgruntled. No decision can totally include all perspectives on an issue.
2. The right to participate does not guarantee the right to succeed.
3. Agency rule making is not totally a democratic process.

On the other hand, there are valuable contributions that the public can make to the Superfund decision-making process.

1. Citizens know best how a decision will affect their interests.
2. Citizens know the local area.
3. Because it is concerned with the making and enforcing of government policy decisions, Superfund decision-making is as much, if not more, a political process than it is a scientific process. Cleanup decisions cannot be determined with the certitude of a mathematic or scientific theorem. Although there are those who would seek to avoid conflict by an appeal to the certainty of science (after all you can't argue with science), an appeal to "good science" cannot eliminate conflict. Correct environmental decisions

lie in the realm of the probable and contingent not the certain and absolute. As an inherently political process, the public must not only be involved but also allowed to be effective in their participation by decision makers. For example, consider Superfund's nine criteria for remedial alternatives evaluation. These criteria do not have scientific or technological certainty or precision. How they apply to perspective decisions, what they mandate and what they do not mandate, how they relate to each other, what they mean, and their significance are the result of political processes, bargaining and decision making. If one takes cost, for instance, how do you determine with scientific and technical certainty whether or not an alternative costs too much? The very standards such as contaminant action levels and the risk assessment process are infused with politics. Often action levels are the result of political bargaining and represent the lowest common denominator of what is acceptable to the various groups fighting about where the levels should be placed. The notion of value neutral decisions in Superfund is unobtainable.

4. Even decisions which are based in science and technology have to be open to public scrutiny and comment. The expert must offer his or her expert opinion to the public in the public realm. The expert's opinion must be tested, analyzed and evaluated in the public realm. We do not, even in environmental decision-making, have a government of experts. To this end, it is important to remember that not all expertise resides in government or the PRPs. Members of the general public often have extensive knowledge, experience, and expertise in the areas under consideration in Superfund. The wanton corporate hubris displayed at a recent meeting on Priority Soils where public input was characterized as the articulation of "feelings" is a disservice and mischaracterization of the value of the public participation process.

The issue of public participation in environmental decision-making is a subset of the larger question of how does one make the bureaucracy accountable and responsive to the public while at the same time ensuring that the bureaucracy will perform its functions with effectiveness and efficiency. The personnel of public agencies such as EPA are not elected. Merit and other current personnel systems can isolate agency personnel from the public. The hiring of agency personnel based on technical and scientific qualification does not ensure that these personnel will be attuned to the public process or will value the public process. There will always be tension between efficiency, effectiveness, public accountability and public responsiveness. No totally satisfactory answer has ever been given to the question: How do you balance the desired independence of decision-makers with

accountability to the public? How do you incorporate “good-science” into decisions that are inherently political?

### ***The Current State of Public Participation in Superfund Decision-Making***

Are there problems with the public participation process in Superfund decision making in Butte?

Based on my participation in the Superfund process, I have reached the following conclusions:

1. The EPA seems to be content to provide public forums often more to provide information to the public rather than to involve the public in Superfund decision-making. This is directly contrary to EPA’s stated position on community involvement in Superfund decision making.
2. The last couple of years have seen overt hostility on the part of some EPA officials to public input and participation, particularly critical public input.
3. Such things as the law, promulgated administrative rules and regulations and the fact that their decisions do have to enjoy some measure of public support limit and define EPA’s commitment to public participation.
4. Some project officers see limited utility in public involvement. Their reasoning is that Superfund decisions require technical and scientific expertise that the general public does not possess and that the public’s wishes do not contribute to the “good science” required for sound Superfund decisions. Their view is that the Superfund process is basically a technical, scientific process that is aided little by public input which process requires too much time and effort for the results received. I think this is a minority view. We have certainly seen this in regard to Phase 1 of the Health Study.
5. More resources need to be devoted to improving the public participation process.
6. Public participation needs to be conducted in a more comprehensive and systematic way. This will require additional resources being committed to public involvement activities. Community involvement is not a major emphasis of the Montana Office of EPA. Look at how community involvement activities have been assigned to RPMs. Under such an arrangement no wonder community involvement activities will not be a priority.
7. There still is need to sensitize agency personnel to the necessity of clear, non-technical communication with the general public. It is possible to communicate clearly with a general audience while not losing scientific precision or legal accuracy. This necessitates giving people who were hired

on the basis of technical competency the additional competency of being effective spokespersons. Little effort has been made to make the Health Study document easily accessible to the general public. Little effort has been made to make the Health Study document understandable to the public. No wonder so few members of the public, exactly three) attended the open house that EPA sponsored on the Health Study. Perhaps the EPA is trying to overwhelm the public with technical reports.

8. The public may be laboring under a misapprehension as to exactly what is the role of public participation in Superfund decision-making. They may think that they have a greater role than is mandated by the law. The EPA has certainly lead the public to believe that public input will matter in the development of the Butte Health Study. Yet, the EPA has back-tracked from its promise that the Health Study will undergo an independent peer review by qualified experts.

At this point I would like to add the comments that I made regarding the Health Study Work Plan. They are still valid today and never have been adequately addressed by the EPA.

#### **Additional Public Comment—Health Study Work Plan**

Submitted by:

Dr. John W. Ray

As the public comment period on the Health Study Work Plan comes to a close, I would like to offer the following process comments:

I don't need to repeat the details of EPA's written commitment, in terms of policy and procedure, to "meaningful public involvement" and to promoting environmental justice.

We will see if the EPA's reaction to the comments received is congruent with the agency's written commitment to promote efficacious public involvement and to promote environmental justice. If the public comments simply get "blown-off" and become only the subject of a perfunctory responsiveness summary, Butte citizens will see once again that the EPA only pays "lip-service" to meaningful public involvement in Superfund decision-making and to environmental justice.

Butte citizens are not happy with the whole Health Study process.

1. From its inception the Health Study process has been problematic. It appears that the Health Study process that we are going through at the present was *necessitated* because the EPA did not like the results of Stacie Barry's study which showed that Superfund had serious problems in Butte. In all my years of involvement in Superfund, I have never seen such a "hatchet job" done on a study and the author of that study.
2. The process has been marked by secrecy. The public has had to constantly demand information about what was going on. Grudgingly, the EPA has released tidbits of information. How can the public participate in Superfund decision-making if it does not know what is happening? It took me countless emails just to find out, for example, who was on the Health Study advisory board and when it was meeting and what were the results of those meetings.
3. Although central Butte has a disproportionate number of low income citizens, environmental justice concerns have been ignored. Look to the work plan and you will see environmental justice is ignored. In this area I fault not only the Montana Office of EPA but Region 8's office in Denver which has an environmental justice staff. I was shocked to find that Region 8, unlike most EPA regions, does not even have an environmental justice action plan.
4. Butte citizens question the independence and validity of the study. It is the old story of the EPA evaluating itself and finding that it has done a good job. This Health Study has no credibility in the community. The EPA publicly laments a lack of citizen participation. Why should citizens participate when their comments have no efficacy? Why should citizens participate when they are criticized for participating? Time and again I have been told by members of the public that participation in Superfund is a total waste of time and effort. Perhaps it is time for Region 8 to become more involved. The above was not always the case. Years back the EPA in Montana was much more open to public input. Today, it is a defensive, hunker down agency. At a minimum, the Montana Office should have a public meeting

and respond publicly to the comments it has received in addition to putting out a responsiveness summary. The whole Health Study design and execution should be subject to independent peer review.

Will things change? We will see. We will see how seriously EPA takes the comments it receives. We will see if the EPA responds in a substantive manner to the comments it receives. We will see if the EPA makes changes in the Health Study Work Plan to respond to citizen input. We will see if EPA takes seriously its commitment to meaningful public involvement and environmental justice.

I am not optimistic. It is hard to hold an agency publicly accountable. We can't vote agency personnel out of office. I suspect all we will get is some perfunctory response to citizen input. Hopefully, I will be proved wrong.

## **Conclusion**

As I have said on numerous occasions, it would be nice to know if Superfund was effective in Butte. One would think that the EPA would like to know this. At the start of the Health Study process, it was hoped that this Health Study would provide the answer. (As a caveat, at the very beginning there were grave doubts about the efficacy of this Health Study. It came after the hatchet job done on Stacie Barry's report which report reached the conclusion that Superfund had not been effective in protecting human health. When the Health Study was announced the results of the Health Study were announced at the same time before any investigation had been done. It was stated that the EPA was sure the Health Study would show that Superfund was working to protect human health. Citizen groups were initially excluded from the Health Study Working Group. The EPA has consistently failed to show how the current Health Study is any kind of improvement over Stacie's study or the other numerous studies that show Superfund has not achieved its goal of protecting public health.)

Nothing so far has allayed these citizen concerns. The latest Health Study report, the so-called Phase I report, continues to be primarily a propaganda piece with serious methodological problems as well as serious public policy failings such as the failing to address environmental justice issues and the failure to meaningfully

involve the public. One of the most damaging things the Montana EPA Office has done is to back-track on its promise that the peer review process would be subjected to an independent peer review that would be conducted during the process of developing the health study and would actually impact the scope, methodology and conduct of the health study.

Because of all of all of these problems with the way the EPA has conducted the Health Study, how can the public have any confidence in its results???????

The Health Study needs to be re-worked to solve its methodological problems, to provide for meaningful public involvement and to address environmental justice issues. Right now the public has little confidence in the EPA. This Health Study does nothing to restore that confidence.

I want to make it clear that my comments relate to THE HEALTH STUDY.

I feel that the Residential Metals Abatement Program, given the limitations imposed on it by EPA, has done a commendable job. The staff is accessible and treats questions and comments seriously. As I said, the problem I have is with the HEALTH STUDY.